DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 9, 2015

Fotona D. D.
Mr. Stojan Trošt
Quality Assurance & Regulatory Affairs Manager
Stegne 7
1000 Ljubljana
Slovenia

Re: K143723
Trade/Device Name: Fotona Dynamis Pro Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ONG
Dated: January 7, 2015
Received: January 9, 2015

Dear Mr. Trošt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143723

Device Name
Fotona Dynamis Pro Family

Indications for Use *(Describe)*

**Dynamis Er:YAG laser (2940 nm wavelength)
The Fotona Dynamis Er:YAG laser is intended for surgical incision/excision, cutting ablation, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

· Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and soft tissue resurfacing;
· ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
· Oral/Maxillofacial Indications: Oral and glossal lesions;
· Ophtalmology Indications: Soft tissue surrounding the eye ;
· Intra-oral soft tissue incision, excision, ablation, coagulation;
· General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation is necessary;
· Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma;
· Genitourinary Indications:lesions of the external genitalia, urethra and anus, penis, scrotum and urethra, vulvar lesions, polyps and familial polyps of the colon;
· Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy;
· The Fotona F-22 Handpiece is intended for:
- In fractionated mode:
Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;
- In non-fractionated mode:
General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation is necessary;
· The Fotona FS-01 Handpiece is intended for:
- Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;

**Dynamis Nd:YAG laser (1064 nm wavelength):
The Fotona Dynamis Nd:YAG laser is intended for incision, ablation,vaporization coagulation and hemostasis of vascular lesions and soft tissue in various dermatological and surgical areas, and for permanent reduction of unwanted hair in Fitzpatrick skin types I - VI.

· Surgical incison, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal, frenectomy and frenotomy;

· Treatment of Aphthous Ulcers;
· Excision and Vaporization of Herpex Simplex I and II;
· Laser assisted uvulopaletoplasty (LAUP);
· Laser assisted lipolysis;
· Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treament regime;
· Treatment of wrinkles;
· Treatment of mild to moderate inflammatory acne vulgaris;
· Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins;
· Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
o Matrixectomy
o Radical nail excision
o Periungual and subungual warts
o Plantar warts
o Neuromas
o Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)
· Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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5. 510(k) Summary

1. SUBMITTER'S INFORMATION

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Contact Person: Stojan Trošt, QA&RA Manager
Phone: + 386 1 5009 299
E-mail: stojan.trost@fotona.com

Date Prepared: Apr 9, 2015

2. DEVICE INFORMATION

Trade Name: **Fotona Dynamis Pro Family**

Common Name: Er:YAG/Nd:YAG Surgical Laser

Classification Name: Powered laser surgical instrument with microbeam\fractional output

Product Code: ONG, GEX

3. PREDICATE DEVICES

- Fotona Dynamis Laser System Family (K101306)
- Fotona F-22 Laser Handpiece, Fotona FS-01 Laser Handpiece (K132806)
- Fotona XP Nd:YAG Laser System Family (K113702)
- Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K093162)
- Fotona XP Nd:YAG Laser System Family (K090126)
- Fotona QX Nd:YAG/KTP Laser System Family (K083889)
- Fotona XP Plus Nd:YAG Family of Laser Systems (K050293)
- Fotona Fidelis Er:YAG Laser System & Accessories (K990243)

4. DEVICE DESCRIPTION

The Fotona Dynamis Pro Laser System Family is based on Er:YAG (2940 nm) and Nd:YAG (1064 nm) laser technology. The laser unit and controls are contained in a

single console. Electrical power is supplied to the console by the facility's power source. The unit combines two flashlamp-pumped laser sources in one housing, with optical cavities containing the Er:YAG and Nd:YAG crystals. A red diode aiming beam (650 nm) is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an articulated arm to an optical manual or scanner hand piece (in the case of the Er:YAG laser), or through an optical fiber delivery system to an optical manual or scanner handpiece (in the case of the Nd:YAG laser). Optionally, the Nd:YAG therapeutic and aiming laser beams can be guided through a fiber having a connector on the proximal end and a bare fiber on the distal end. Fotona's power supply Variable Square Pulse (VSP) Technology, integrated into the laser system, allows control of the laser energy and the laser pulse duration. The user activates laser emission by means of a footswitch.

The Fotona Dynamis Pro Family is designed to operate in single wavelength (Nd:YAG or Er:YAG) configurations (models) and dual wavelength (Nd:YAG and Er:YAG) configurations (models).

5. INTENDED USE

Dynamis Er:YAG laser (2940 nm wavelength)

The Fotona Dynamis Pro Er:YAG laser is intended for surgical incision/excision, cutting, ablation, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and soft tissue resurfacing;
- ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
- Oral/Maxillofacial Indications: Oral and glossal lesions;
- Ophtalmology Indications: Soft tissue surrounding the eye ;
- Intra-oral soft tissue incision, excision, ablation, coagulation;
- General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation is necessary;
- Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma;
- Genitourinary Indications:lesions of the external genitalia, urethra and anus, penis, scrotum and urethra, vulvar lesions, polyps and familial polyps of the colon;
- Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy;
- The Fotona F-22 Handpiece is intended for:

– In fractionated mode:

Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;

- In non-fractionated mode:

General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation is necessary;

- The Fotona FS-01 Handpiece is intended for:
- Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;

Dynamis Nd:YAG laser (1064 nm wavelength):

The Fotona Dynamis Pro Nd:YAG laser is intended for incision, ablation,vaporization coagulation and hemostasis of vascular lesions and soft tissue in various dermatological and surgical areas, and for permanent reduction of unwanted hair in Fitzpatrick skih types I - VI.

- Surgical incison, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal, frenectomy and frenotomy;
- Treatment of Aphthous Ulcers;
- Excision and Vaporization of Herpex Simplex I and II;
- Laser assisted uvulopaletoplasty (LAUP);
- Laser assisted lipolysis;
- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treament regime;
- Treatment of wrinkles;
- Treatment of mild to moderate inflammatory acne vulgaris;
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins;
- Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
    - Matrixectomy
    - Radical nail excision
    - Periungual and subungual warts
    - Plantar warts
    - Neuromas

- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.);
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona Dynamis Pro Family has the same technological and design characteristics (design, chemical composition, energy source; wavelength, active medium, cooling system, power supply, beam delivery, controls, housing) as the previously cleared devices: Fotona Dynamis Er:YAG/Nd:YAG Laser System Family (K101306), Fotona F-22 Laser Handpiece (F-Runner), Fotona FS-01 Laser Handpiece (K132806), Fotona XP Nd:YAG Laser System Family (K113702), Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K093162), Fotona XP Nd:YAG Laser System Family (K090126), Fotona QX Nd:YAG/KTP Laser System Family (K083889), Fotona XP Plus Nd:YAG Family of Laser Systems (K050293), and Fotona Fidelis Er:YAG Laser System & Accessories (K990243).

The output characteristics are for the intended use the same as those of the predicate devices. All systems are based on VSP (Variable Square Pulse) power supply technology. All lasers utilize class I aiming beams which pose no hazard to the user. All systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection and avoids hazard incidence. All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity. The risk and benefits for the Fotona Dynamis Pro Family are identical to the predicate devices when used for similar clinical applications.

A comparison of the technical specifications for the intended use of the Dynamis Pro Family with the previously cleared devices is provided in Table 1 (for the Nd:YAG wavelength) and Table 2 (for the Er:YAG wavelength) below.

Table 1: Comparison table of the technical output characteristics for the intended use between the Fotona Dynamis Family and previously cleared devices for the Er:YAG laser wavelength

Er:YAG 2940 nm	**Fotona Dynamis Er:YAG/Nd:YAG Laser System Family (K101306)**	**Fotona Fidelis Er:YAG Laser System & Accessories (K990243)**	**Fotona F-22 Laser Handpiece (F-Runner), Fotona FS-01 Laser Handpiece (K132806)**	**Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K093162)**	**Fotona Dynamis Pro Family (new submission)**
Wavelength	2940 nm	2940 nm	2940 nm	2940 nm	2940 nm
Laser media	Flashlamp pumped solid state Er:YAG rod	Flashlamp pumped solid state Er:YAG rod	Flashlamp pumped solid state Er:YAG rod	Flashlamp pumped solid state Er:YAG rod	Flashlamp pumped solid state Er:YAG rod
Aiming beam	650 nm	650 nm	650 nm	650 nm	650 nm
Output mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	30 – 3000 mJ	40 – 1000 mJ	30 – 3000 mJ	20 – 1500 mJ	30 – 3000 mJ
Pulsewidth	100 - 1500 µs	75 – 1000 µs	100 - 300 µs	50 – 1000 µs	100 - 1500 µs

Repetition rate	up to 50 Hz	up to 50 Hz	up to 50 Hz	up to 50 Hz	up to 50 Hz
Power	up to 20 W	up to 15 W	up to 20 W	up to 20 W	up to 20 W
Beam Delivery	Articulated arm	Articulated arm	Articulated arm	Articulated arm	Articulated arm
User interface	Push button control	Push button control	Push button control	LCD Toucscreen	LCD Touchscreen

Table 2: Comparison table of the technical output characteristics for the intended use between the Fotona Dynamis Family and previously cleared devices for the Nd:YAG laser wavelength

Nd:YAG	**Fotona Dynamis Laser System Family (K101306)**	**Fotona XP Nd:YAG Laser System Family (K113702, K090126)**	**Fotona XP Plus Nd:YAG Family of Laser Systems (K050293)**	**Fotona QX Nd:YAG/KTP Laser System Family (K083889)**	**Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K093162)**	**Fotona Dynamis Pro Family (new submission)**
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm	1064 nm	1064 nm
Laser media	Flashlamp pumped solid state Nd:YAG rod	Flashlamp pumped solid state Nd:YAG rod	Flashlamp pumped solid state Nd:YAG rod	Flashlamp pumped solid state Nd:YAG rod	Flashlamp pumped solid state Nd:YAG rod	Flashlamp pumped solid state Nd:YAG rod
Aiming beam	650 nm	650 nm	650 nm	650 nm	650 nm	650 nm
Output mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	up to 50 J	up to 20 J	up to 120 J	5J	up to 10J	up to 50 J
Pulse duration	0.1 – 50 ms	0.1-50 ms	0.1-300 ms	0.25 ms	0.1-25 ms	0.1 – 50 ms
Repetition rate	up to 100 Hz	up to 100 Hz	up to 75 Hz	0.5 – 2.2 Hz	up to 100 Hz	up to 100 Hz
Power	up to 80 W	up to 30 W	up to 130 W	11W	up to 15 W	up to 80 W
Beam delivery	Fiber	Fiber	Fiber	Articulated arm	Fiber	Fiber
User interface	Push button control	Push button control	Push button control	Push button control	LCD Touchscreen	LCD Touchscreen

7. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fotona Dynamis Pro Family is substantially equivalent in terms of indications for use and technology based on technical characteristics to the following predicate devices when used according to its intended use: Fotona Dynamis Er:YAG/Nd:YAG Laser System Family (K101306), Fotona F-22 Laser Handpiece (F-Runner), Fotona FS-01 Laser Handpiece (K132806), Fotona XP Nd:YAG Laser System Family (K113702), Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K093162), Fotona XP Nd:YAG Laser System Family (K090126), Fotona QX Nd:YAG/KTP Laser System Family (K083889), Fotona XP Plus Nd:YAG Family of Laser Systems (K050293), and Fotona Fidelis Er:YAG Laser System & Accessories (K990243).

8. TESTING

Clinical testing:

No clinical testing was needed.

Fotona Dynamis Pro Family is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards including:

- 21 CFR 1040.10 Performance Standards for Light – Emitting Products, Laser products
- 21 CFR 1040.11 Performance Standards for Light – Emitting Products, Specific purpose laser products
- **IEC 60601-1 Ed.3.0: 2005 + Corr 1. 2006 + Corr 2. 2007; EN 60601-1: 2006/AC:2010** Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2: 2007, EN 60601-1-2: 2007; EN 60601-1-2:2007/AC:2010** Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility – Requirements and tests.
- **IEC 60601-2-22: 2007; EN 60601-2-22:2013** General requirements for basic safety and essential performance. Part 2: Particular requirements for safety diagnostic and therapeutic laser equipment.
- **IEC 60825-1: 2007; EN 60825-1: 2007** Safety of laser products. Part 1: Equipment classification and reuirements.
- **EN ISO 14971: 2012** Medical devices – application of risk management to medical devices
- **IEC 62304:2005; EN 62304: 2006** Medical device Software – software life-cycle process
- **ISO 17664: 2004** Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- **IEC 62366: 2007/ A1:2014; EN 62366: 2008** Medical devices - Application of usability engineering to medical devices
- **IEC 60601-1-6: 2010; EN 60601-1-6: 2010** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Laboratory testing has been conducted to validate and verify that the proposed Fotona Dynamis Pro Family meets all design specifications and is substantially equivalent to the predicate devices.